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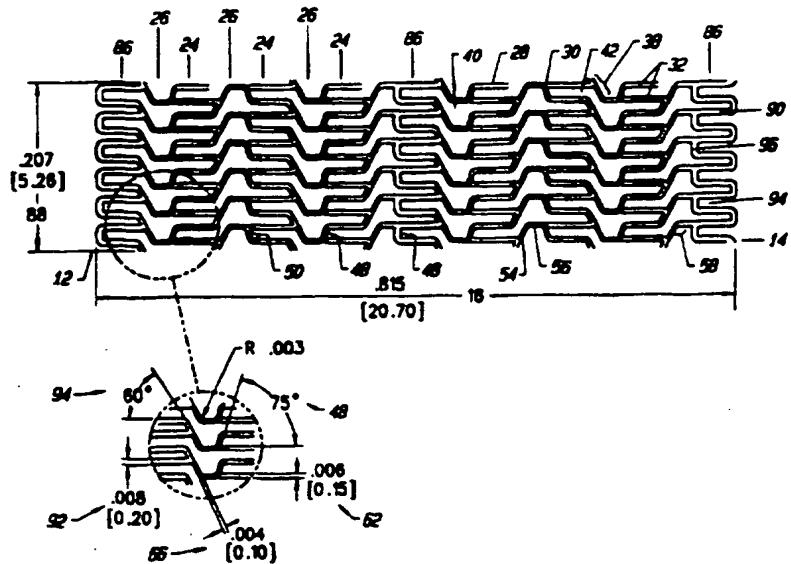
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(54) Title: INTRAVASCULAR STENT



(57) Abstract

A stent assembly includes a balloon and an expandable stent positioned at an exterior of the balloon. The stent includes a first expansion strut. A plurality of the first expansion struts form a first expansion column. A plurality of second expansion struts form a second expansion column. A plurality of the first connecting struts form a first connecting strut column. Each of a first expansion strut of the first expansion column is coupled to a second expansion strut of the second expansion column. The first connecting strut includes a proximal section coupled to a distal section and at least a portion of the first connecting strut includes a first linear section and a first slant angle.

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Intravascular Stent

Cross-reference to Related Applications

5 This application claims the benefit of Provisional Patent Application No. 60/017,484 filed April 26, 1996, the disclosure of which is incorporated by reference. This application is related to U.S. Patent Application Serial No. _____, (Attorney Docket No. 18461.702), filed March 25, 1997, entitled "Intravascular Stent" and U.S. Patent Application Serial No. _____, (Attorney Docket No. 18461.703), filed March 25, 1997, 10 entitled "Intravascular Stent", both having same named inventor G. David Jang and incorporated by reference.

BACKGROUND OF THE INVENTION

15 **Field of the Invention:**

This invention relates to intravascular stents, and more particularly to an intravascular stent which provides easy introduction through tortuous sections of vessels.

20 **Description of the Related Art:**

Angioplasty, either coronary or general vascular, has advanced to become the most effective means for revascularization of stenosed vessels. In the early 1980's, angioplasty first became available for clinical practice in the coronary artery, and has since proven an effective alternative to conventional bypass graft surgery. Balloon catheter dependent angioplasty has consistently proven to be the most reliable and practical interventional procedure. Other ancillary technologies such as laser based treatment, or directional or rotational arthrectomy, have proven to be either of limited effectiveness or dependent on balloon angioplasty for completion of the intended procedure. Restenosis following balloon-based angioplasty is the most serious drawback and is especially prevalent in the coronary artery system.

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Many regimens have been designed to combat restenosis, with limited success, including laser based treatment and directional or rotational arthrectomy. Intravascular stenting, however, noticeably reduces the restenosis rate following angioplasty procedures. The procedure for intravascular stent placement typically involves pre-dilation of the target vessel using balloon angioplasty, followed by deployment of the stent, and expansion of the stent such that the dilated vessel walls are supported from the inside.

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The intravascular stent functions as scaffolding for the lumen of a vessel. The scaffolding of the vessel walls by the stent serve to: (a) prevent elastic recoil of the dilated vessel wall, (b) eliminate residual stenosis of the vessel, a common occurrence in balloon angioplasty procedures, (c) maintain the diameter of the stented vessel segment slightly larger than the native unobstructed vessel segments proximal and distal the stented segment and (d) as indicated by the latest clinical data, lower the restenosis rate. Following an angioplasty procedure, the restenosis rate of stented vessels has proven significantly lower than for unstented or otherwise treated vessels; treatments include drug therapy and other methods mentioned previously.

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Another benefit of vessel stenting is the potential reduction of emergency bypass surgery arising from angioplasty procedures. Stenting has proven to be effective in some cases for treating impending closure of a vessel during angioplasty. Stenting can also control and stabilize an unstable local intimal tear of a vessel caused by normal conduct during an angioplasty procedure. In some cases, an incomplete or less than optimal dilatation of a vessel lesion with balloon angioplasty can successfully be opened up with a stent implant.

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Early in its development, the practice of stenting, especially in coronary arteries, had serious anticoagulation problems. However, anticoagulation techniques have since been developed and are becoming simpler and more effective. Better and easier to use regimens are continuously being introduced, including simple outpatient anticoagulation treatments, resulting in reduced hospital stays for stent patients.

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An example of a conventional stent patent is US 5,102,417 (hereafter the Palmaz Patent). The stent described in the Palmaz Patent consists of a series of elongated tubular members having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular members. The tubular members are connected by at least one flexible connector member.

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The unexpanded tubular members of the Palmaz Patent are overly rigid so that practical application is limited to short lengths. Even with implementation of the multilink design with flexible connector members connecting a series of tubular members, longer stents can not navigate tortuous blood vessels. Furthermore, the rigidity of the unexpanded stent increases the risk of damaging vessels during insertion. Foreshortening of the stent during insertion complicates accurate placement of the stent and reduces the area that can be covered by the expanded stent. There is, further, no method of programming the stent diameter along its longitudinal axis to achieve a tapered expanded stent, and no method of reenforcement of stent ends or other regions is provided for.

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Another example of a conventional stent patent is WO 96/03092, the Brun patent. The stent described in the Brun patent is formed of a tube having a patterned shape, which has first and second meander patterns. The even and odd first meander patterns are 180 degrees out of phase, with the odd patterns occurring between every two even patterns. The second meander patterns run perpendicular to the first meander patterns, along the axis of the tube.

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Adjacent first meander patterns are connected by second meander patterns to form a generally uniform distributed pattern. The symmetrical arrangement with first and second meander patterns having sharp right angled bends allows for catching and snagging on the vessel wall during delivery. Furthermore, the large convolutions in the second meander pattern are not fully straightened out during expansion reducing rigidity and structural strength of the expanded stent. There is, further, no method of programming the stent diameter along its longitudinal axis to achieve a tapering stent design, and no method of reenforcement of stent ends or other regions is provided for.

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These and other conventional stent designs suffer in varying degrees from a variety of drawbacks including: (a) inability to negotiate bends in vessels due to columnar rigidity of the unexpanded stent; (b) lack of structural strength, radial and axial lateral, of the unexpanded stent; (c) significant foreshortening of the stent during expansion; (d) limited stent length; (e) constant expanded stent diameter; (f) poor crimping characteristics; and (g) rough surface modulation of the unexpanded stent.

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There is a need for a stent with sufficient longitudinal flexibility in the unexpanded state to allow for navigation through tortuous vessels. There is a further need for a stent that is structurally strong in the unexpanded state such that risk of damage or distortion during delivery is minimal. A further need exists for a stent that maintains substantially the same longitudinal length during expansion to allow greater coverage at the target site and simplify proper placement of the stent. Yet a further need exists for a stent design with sufficient longitudinal flexibility that long stents of up to 100 mm can be safely delivered through tortuous vessels. There is a need for a stent that is configured to expand to variable diameters along its length, such that a taper can be achieved in the expanded stent to match the natural taper of the target vessel. A need exists for a stent which, (i) can be crimped tightly on the expansion balloon while maintaining a low profile and flexibility, (ii) has a smooth surface modulation when crimped over a delivery balloon, to prevent catching and snagging of the stent on the vessel wall during delivery or (iii) with reinforcement rings on the ends or middle or both to keep the ends of the stent securely positioned against the vessel walls of the target blood vessel.

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SUMMARY OF THE INVENTION

Accordingly an object of the present invention is to provide a scaffold for an interior lumen of a vessel.

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Another object of the invention is to provide a stent which prevents recoil of the vessel following angioplasty.

A further object of the invention is to provide a stent that maintains a larger vessel lumen compared to the results obtained only with balloon angioplasty.

5 Yet another object of the invention is to provide a stent that reduces foreshortening of a stent length when expanded.

Another object of the invention is to provide a stent with increased flexibility when delivered to a selected site in a vessel.

A further object of the invention is to provide a stent with a low profile when crimped over a delivery balloon of a stent assembly.

10 Yet a further object of the invention is to provide a stent with reduced
tupeling of the vessel wall.

Another object of the invention is to provide a chain mesh stent that reduces vessel "hang up" in a tortuous vessel or a vessel with curvature.

15 These and other objects of the invention are achieved in a stent in a non-expanded state. A first expansion strut pair includes a first expansion strut positioned adjacent to a second expansion strut. A joining strut of the first expansion strut pair couples the first and second expansion struts at a distal end of the first expansion strut pair. A plurality of the first expansion strut pair form a first expansion column. A second expansion strut pair includes a first expansion strut positioned adjacent to a second expansion strut. A joining strut of the second expansion strut pair couples the first and second expansion struts of the second expansion strut pair at a proximal end of the second expansion strut pair. A plurality of the second expansion strut pair form a second expansion column. A first connecting strut includes a first connecting strut proximal head section and a first connecting strut distal tail section. The head section is coupled to the distal end of the first expansion strut pair in the first expansion column, and the tail section is coupled to the proximal end of the second expansion strut pair of the second expansion column. A plurality of the first connecting strut form a first connecting strut column that couples the first expansion column to the second expansion column. The tail section extends in a first lateral direction relative to a longitudinal axis of the head section to form a

first slant angle. A third expansion strut pair includes a first expansion strut positioned adjacent to a second expansion strut. A third joining strut of the third expansion strut pair couples the first and second expansion struts at a proximal end of the third expansion strut pair. A plurality of the third expansion strut pair form a third expansion column. The first expansion strut of the first expansion strut pair in the first expansion column have a longitudinal axis that is parallel to and offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column. The second expansion strut of the third expansion strut pair in the third expansion column has a longitudinal axis that is parallel to and offset from a longitudinal axis of the first expansion strut of the second expansion strut pair of the second expansion column. A second connecting strut includes a proximal head section and a distal tail section. The head section is coupled to the distal end of the second expansion strut pair in the second expansion column. The tail section is coupled to the proximal end of the third expansion strut pair of the third expansion column. A plurality of the second connecting strut form a second connecting strut column that couples the second expansion column to the third expansion column. The tail section extends in a second lateral direction relative to a longitudinal axis of the head section to form a second slant angle that extends in an opposite direction from the first lateral direction. A ratio of a number of expansion struts in an expansion strut column to a number of connecting struts in a connecting strut column is 2 to 1. The first slant angle reduces a fore shortening of the stent between the first and second expansion columns when the stent is in an expanded state.

In another embodiment, a stent assembly includes a balloon and an expandable stent positioned at an exterior of the balloon. The stent includes a first expansion strut. A plurality of the first expansion struts form a first expansion column. A plurality of second expansion struts form a second expansion column. A plurality of the first connecting struts form a first connecting strut column. Each of a first expansion strut of the first expansion column is coupled to a second expansion strut of the second expansion column.

The first connecting strut includes a proximal section coupled to a distal section and at least a portion of the first connecting strut includes a first linear section and a first slant angle.

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BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A is a side elevation view of the pre-expansion mode of an embodiment of the stent of the present invention;

Fig. 1B is a cross sectional view of an embodiment of the stent of the present invention;

10 Fig. 1C is a longitudinal cross sectional view of an embodiment of the stent of the present invention;

Fig. 2A is a scale drawing of the strut pattern of an embodiment of the stent of the present invention.

Fig. 2B is an expanded view of a section of the pattern of Figure 2A.

15 Fig. 3A is a schematic illustration of the pre-expansion mode of an embodiment of the stent of the present invention.

Fig. 3B is a schematic illustration of the post-expansion mode of an embodiment of the stent of the present invention.

20 Fig. 4A is a scale drawing including dimensions of an embodiment of the stent of the present invention.

Fig. 4B is an enlarged section of the scale drawing of Figure 4A.

Fig. 5 is a scale drawing of an embodiment of the stent of the present invention with a tapered diameter in its post-expansion mode.

25 Fig. 6A is a scale drawing of an embodiment of the stent of the present invention with reenforcement expansion columns.

Fig. 6B is a perspective view of the embodiment of Figure 6A.

Fig. 7A is a scale drawing of an embodiment of the stent of the present invention including relief notches at strut joints to increase flexibility of the joints.

30 Fig. 7B is an enlarged region of the embodiment of Figure 7A.

Fig. 7C is an enlarged view of a single connecting strut joining two expansion strut pairs in accordance with the embodiment of Figure 7A.

Fig. 8A is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention.

5 Fig. 8B is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention.

Fig. 8C is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention.

10 Fig. 8D is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention.

Fig. 8E is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention.

Fig. 9 is a delivery balloon catheter, illustrating a method of deliver of a stent in accord with the present invention.

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DETAILED DESCRIPTION

A first embodiment of the present invention is shown in Figures 1A, 1B, 1C, 2A and 2B. Referring to Figure 1A, an elongate hollow tubular stent 10 in an unexpanded state is shown. A proximal end 12 and a distal end 14 define a longitudinal length 16 of stent 10. The longitudinal length 16 of the stent 10 can be as long as 100 mm or longer. A proximal opening 18 and a distal opening 20 connect to an inner lumen 22 of stent 10. Stent 10 can be a single piece, without any seams or welding joints or may include multiple pieces.

20 Stent 10 is constructed of two to fifty or more expansion columns or rings 24 connected together by interspersed connecting strut columns 26. The first column on the proximal end 12 and the last column on the distal end 14 of stent 10 are expansion columns 24.

25 Expansion columns 24 are formed from a series of expansion struts 28, and joining struts 30. Expansion struts 28 are thin elongate members arranged so that they extend at least in part in the direction of the longitudinal axis of stent 10. When an outward external force is applied to stent 10 from the inside by an

expansion balloon or other means, expansion struts 28 are reoriented such that they extend in a more circumferential direction, i.e along the surface of cylindrical stent 10 and perpendicular to its longitudinal axis. Reorientation of expansion struts 28 causes stent 10 to have an expanded circumference and 5 diameter. In Figure 1A, expansion struts 28 of unexpanded stent 10 are seen to extend substantially parallel to the longitudinal axis of stent 10.

Expansion struts 28 are joined together by joining struts 30 to form a plurality of expansion strut pairs 32. Expansion strut pairs have a closed end 34 and an open end 36. Additional joining struts 30 join together expansion struts 10 28 of adjacent expansion strut pairs 32, such that expansion struts 28 are joined alternately at their proximal and distal ends to adjacent expansion struts 28 to form expansion columns 24. Each expansion column 24 contains a plurality, typically eight to twenty, twenty to sixty, or larger of expansion struts 28.

Connecting struts 38 connect adjacent expansion columns 24 forming a 15 series of interspersed connecting strut columns 26 each extending around the circumference of stent 10. Each connecting strut 38 joins a pair of expansion struts 28 in an expansion column 24 to an adjacent pair of expansion struts 28 in an adjacent expansion column 24. For stent 10 of Figure 1A, the ratio of expansion struts 28 in an expansion column 24 to connecting struts 38 in a 20 connecting strut column 26 is two to one; however, this ratio in general can be x to 1 where x is greater or less than two. Furthermore, since the stent 10 of Figure 1A begins with an expansion column 24 on the proximal end 12 and ends with an expansion column 24 on the distal end 14, if there are n expansion 25 columns 24 with m expansion struts 28 per column, there will be $m-1$ connecting strut columns 26, and $n(m-1)/2$ connecting struts 38.

The reduced number of connecting struts 38 in each connecting strut column 26, as compared to expansion struts 28 in each expansion column 24, allows stent 10 to be longitudinally flexible. Longitudinal flexibility can be further increased by using a narrow width connecting strut, providing additional 30 flexibility and suppleness to the stent as it is navigated around turns in a natural blood vessel.

At least a portion of the open spaces between struts in stent 10 form asymmetrical cell spaces 40. A cell space is an empty region on the surface of stent 10, completed surrounded by one or a combination of stent struts, including expansion struts 28, connecting struts 38, or joining struts 30.

5 Asymmetrical cell spaces 40 are cell spaces which have no geometrical symmetry i.e. no rotation, reflection, combination rotation and reflection or other symmetry.

10 Asymmetrical cell spaces 40 in Figure 1A are surrounded by a first expansion strut pair 32 in a first expansion column 24, a first connecting strut 38, a second expansion strut pair 32 in an adjacent expansion column 24, a first joining strut 30, a second connecting strut 38, and a second joining strut 30. Furthermore, expansion strut pairs 32 of asymmetrical cell space 40 may be circumferentially offset i.e. have longitudinal axes that are not collinear and have their open ends 36 facing each other. The space between two expansion struts 15 of an expansion strut pair 32 is known as a loop slot 42.

Figure 1B shows inner lumen 22, radius 44 and stent wall 46 of stent 10. Stent wall 46 consists of stent struts including expansion struts 28, connecting struts 38 and joining struts 30.

20 Figure 1C shows, proximal end 12, distal end 14, longitudinal length 16, inner lumen 22, and stent wall 46 of stent 10. Inner lumen 22 is surrounded by stent wall 46 which forms the cylindrical surface of stent 10.

25 Referring now to Figures 2A and 2B, joining struts 30 of stent 10 are seen to extend at an angle to the expansion struts 28, forming a narrow angle 48 with one expansion strut 28 in an expansion strut pair 32 and a wide angle 50 with the other expansion strut 28 of an expansion strut pair 32. Narrow angle 48 is less than ninety degrees, while wide angle 50 is greater than ninety degrees. Joining struts 30 extend both longitudinally along the longitudinal axis of stent 10 and circumferentially, along the surface of the stent 10 perpendicular its longitudinal axis.

30 Expansion strut spacing 52 between adjacent expansion struts 28 in a given expansion column 24 are uniform in stent 10 of Figures 2A and 2B;

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however, non-uniform spacings can also be used. Expansion strut spacings 52 can be varied, for example, spacings 52 between adjacent expansion struts 28 in an expansion column 24 can alternate between a narrow and a wide spacing. Additionally, spacings 52 in a single expansion column 24 can differ from other spacings 52 in other columns 24.

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It is noted that varying expansion strut spacings 52 which form the loop slots 42 results in variable loop slot widths. Furthermore, the longitudinal axis of the loop slots 42 need not be collinear or even parallel with the longitudinal axis of loop slots 42 of an adjacent expansion column 24. Figures 2A and 2B show an arrangement of expansion struts 28 such that collinear, parallel adjacent loop slots 42 are formed, but non-collinear and non-parallel loop slots 42 can also be used.

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Additionally the shape of loop slots 42 need not be the same among loop slots of a single or multiple expansion columns 24. The shape of loop slots 42 can be altered by changing the orientation or physical dimensions of the expansion struts 28 and/or joining struts 30 which connect expansion struts 28 of expansion strut pairs 32 defining the boundaries of loop slots 42.

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Connecting struts 38 couple adjacent expansion columns 24, by connecting the distal end of an expansion strut pair in one expansion column 24 to the proximal end of an adjacent expansion strut pair 32 in a second expansion column 24. Connecting struts 38 of Figures 2A and 2B are formed from two linear sections, a first linear section 54 being joined at its distal end to a second linear section 56 at its proximal end to form a first slant angle 58.

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The first linear section 54 of a connecting strut 38 is joined to expansion strut 28 at the point where joining strut 30 makes narrow angle 48 with expansion strut 28. First linear section 54 extends substantially collinear to joining strut 30 continuing the line of joining strut 30 into the space between expansion columns 24. The distal end of the first linear section 54 is joined to the proximal end of the second linear section 56 forming slant angle 58. Second linear section 56 extends substantially parallel to expansion struts 28 connecting at its distal end to joining strut 30 in an adjacent expansion column 24. The

distal end of second linear section 56 attaches to expansion strut 28 at the point where joining strut 30 makes narrow angle 48 with expansion strut 28. Further, joining strut 30 can have a second slant angle with a width that can be the same or different from the width of the first slant angle.

5 Figures 2A and 2B show connecting struts 38 and joining struts 30 slanted relative to the longitudinal axis of stent 10, with the circumferential direction of the slanted struts alternating from column to adjacent column. Circumferential direction refers to the handedness with which the slanted struts wind about the surface of the stent 10. The circumferential direction of the slant of connecting strut first linear sections 54 in a connecting strut column 26 is 10 opposite the circumferential direction of the slant of connecting strut first linear sections 54 in an adjacent connecting strut column 26. Similarly, the circumferential direction of the slant of joining struts 30 in an expansion column 24 is opposite the circumferential direction of the slant of joining struts 30 in an adjacent expansion column 24. Alternating circumferential slant directions of connecting struts 38 and joining struts 30 prevents axial warping of stent 10 during deliver and expansion. Other non-alternating slant direction patterns can 15 also be used for connecting struts 38 or joining struts 30 or both.

20 Figure 3A and 3B show a schematic illustration of a stent design according to the present invention in an unexpanded and expanded state respectively. The design is depicted as a flat projection, as if stent 10 were cut lengthwise parallel to its longitudinal axis and flattened out. The connecting struts 38 consist of first and second linear sections 54 and 56 forming slant angle 58 at pivot point 60. An asymmetrical cell space 40 is formed by expansion strut pairs 32, connecting struts 38 and joining struts 30. Multiple interlocking 25 asymmetrical cell spaces 40 make up the design pattern.

28 As the stent is expanded, see Figure 3B, the expansion strut pairs 32 spread apart at their open ends 36, shortening the length of expansion struts 28 along the longitudinal axis of the cylindrical stent. The longitudinal shortening of expansion struts 28 during expansion is countered by the longitudinal 30 lengthening of connecting struts 38. The widening of slant angle 58 during

expansion straightens connecting struts 38 and lengthens the distance between the coupled expansion strut pairs 32. The lengthening of the distance between coupled expansion strut pairs 32 substantially compensates for the longitudinal shortening of expansion struts 28. Thus, the stent has substantially constant 5 unexpanded and expanded longitudinal lengths.

When the stent is expanded, each expansion column 24 becomes circumferentially stretched, enlarging the space between struts. The interlinking of expansion columns 24 by connecting struts 38 that have been straightened through the expansion process gives the stent 10 a high radial support strength. 10 The entire stent 10 when expanded is unitized into a continuous chain mesh of stretched expansion columns 24 and connecting strut columns 26 forming an asymmetrical interlocking cell geometry which resists collapse both axially and radially. When the stent is expanded it has increased rigidity and fatigue tolerance.

15 In addition, efficient bending and straightening of connecting struts 38 at pivot points 60 allows increased longitudinal flexibility of the stent. For the stent to bend longitudinally, at least some of connecting struts 38 are forced to bend in their tangent plane. The tangent plane of a specific connecting strut 38 refers to the plane substantially tangent to the cylindrical surface of the stent at that 20 connecting strut 38. The width of connecting struts 38 is typically two to four, or more times the thickness, which makes connecting struts 38 relatively inflexible when bending in their tangent plane. However, pivot points 60 in connecting struts 38 provide connecting struts 38 a flexible joint about which to more easily bend increasing longitudinal flexibility of the stent.

25 Referring to Figures 4A and 4B, a variation of the first embodiment of stent 10 of the present invention is shown. In this variation, stent 10 has a length 16 of 33.25 mm and an uncrimped and unexpanded circumference 88 of 5.26 mm. Fifteen expansion columns 24 are interspersed with connecting strut columns 26. Each expansion column 24 consists of twelve expansion struts 28 joined alternately at their proximal and distal ends by joining struts 30 forming 30 six expansion strut pairs 32. Expansion struts 28 are aligned parallel to the

longitudinal axis of cylindrical stent 10. Joining struts 30 form a narrow angle 48 and a wide angle 50 with the respective expansion struts 28 of expansion strut pairs 32. Adjacent expansion columns 24 employ alternating circumferential slant directions of joining struts 30.

5 In this variation of the first embodiment, expansion strut width 62 is .20 mm, expansion strut length 64 is 1.51 mm, and connecting strut width 66 is .13 mm. Distance 68 from the outer edge of a first expansion strut 28 to the outer edge of a second adjacent expansion strut 28 in the same expansion column 24 is .64 mm, leaving a loop slot width 70 of .24 mm.

10 In this variation of the first embodiment, connecting struts 38 consist of a slanted first linear section 54 joined to a second linear section 56 at a slant angle 58. First linear section 54 is slightly longer than second linear section 56 and is attached at its proximal end to an expansion strut 28 in an expansion column 24. The attachment of the proximal end of first linear section 54 to expansion strut 28 is at the point where joining strut 30 makes narrow angle 48 with expansion strut 28. First linear section 54 extends substantially collinear to joining strut 30 attaching at its distal end to the proximal end of second linear section 56 to form slant angle 58. Second linear section 56 extends substantially collinear to expansion struts 28, attaching at its distal end to an expansion strut 28 in an adjacent expansion column 24. The attachment occurs at the point where expansion strut 28 forms narrow angle 48 with joining strut 30. Joining struts 30 and connecting strut first linear sections 54 slant in alternating circumferential directions from column to adjacent column.

15 The joining of connecting struts 38 and expansion struts 28 at the point where narrow angle 48 is formed aids smooth delivery of stent 10 by streamlining the surface of the unexpanded stent and minimizing possible catching points. Bare delivery of stent 10 to the target lesion in a vessel will thus result in minimal snagging or catching as it is navigated through turns and curvatures in the vessel. Stent 10 behaves like a flexible, tubular sled as it is moved forward or backward in the vessel on the delivery catheter, sliding

through tortuous vessels and over irregular bumps caused by atherosclerotic plaques inside the vessel lumen.

When fully expanded Stent 10 of Figures 4A and 4B has an internal diameter of up to 5.0 mm, while maintaining an acceptable radial strength and 5 fatigue tolerance. The crimped stent outer diameter can be as small as 1.0 mm or less depending on the condition of the underlying delivery balloon profile; A small crimped outer diameter is especially important if stent delivery is to be attempted without predilation of the target site. When the stent is optimally crimped over the delivery balloon, the surface of the crimped stent is smooth 10 allowing for no snagging of the stent struts during either forward or backward movement through a vessel.

Figure 5 shows a second embodiment of the present invention in which the stent 10 in its expanded form has a gradual taper from proximal end 12 to distal end 14. The shaded segments 72, 74, 76, 78, 80, 82 and 84 of expansion 15 struts 28 represent regions of expansion struts 28 to be removed. Removal of the shaded segments 72, 74, 76, 78, 80, 82 and 84 provides stent 10 with a gradual taper when expanded with distal end 14 having a smaller expanded diameter than proximal end 12. The degree of shortening of the expanded diameter of the stent 10 at a given expansion column 24 will be proportional to the length of the 20 removed segment 72, 74, 76, 78, 80, 82, or 84 at that expansion column 24. In the expanded stent 10 the shortened expansion struts 28 will have a shortened component along the circumference of the stent resulting in a shortened circumference and diameter. The tapered diameter portion can be positioned anywhere along the length of stent 10, and the tapering can be made more or less 25 gradual by removing appropriately larger or smaller portions of the expansion struts 28 in a given expansion column 24. Tapering is especially important in long stents, longer than 12 mm, since tapering of blood vessels is more pronounced over longer lengths. A long stent with a uniform stent diameter can only be matched to the target vessel diameter over a short region. If the proximal vessel size is matched with the stent diameter, the expanded distal end 30 of the stent will be too large for the natural vessel and may cause an intimal

dissection of the distal vessel by stent expansion. On the other hand, if the distal vessel size is matched with the stent diameter, the proximal end of the expanded stent will be too small to set inside the vessel lumen. It is therefore desirable to have a stent with a tapered expanded diameter.

5 Another way achieve a tapered expanded stent is to change the stiffness of the stent struts, expansion struts, connecting struts or joining struts such that the stiffness of the struts varies along the length of the stent. The stiffness of the struts can be changed by altering length, width or thickness, adding additional stiffening material, using a chemical or mechanical means to alter the physical properties of the stent material, or applying one or a series of elastic elements 10 about the stent.

15 Along with the use of a tapered diameter stent, a matching tapered balloon catheter would ideally be made for delivery and deployment of the tapered diameter stent. The method of using a tapered matching balloon catheter with a tapered diameter stent is within the scope of the present invention.

20 Using a tapered balloon to expand a non-tapered stent will also achieve a tapered expanded stent; however, since no metal is removed from the stent, the stent is tapered as a result of incomplete expansion. The stent will therefore have increased metal fraction at the tapered end resulting in increased risk of acute thrombosis. Metal fraction is the proportion of the surface of the expanded stent covered by the stent strut material. Shortening the expansion struts as shown in Figure 5 allows for a tapered expanded stent with substantially 25 constant metal fraction along its length.

25 A third embodiment of the present invention shown in Figures 6A and 6B has multiple reenforcement expansion columns 86 placed along the length of the stent 10. The Reenforcement columns 86 are placed along the stent length to provide additional localized radial strength and rigidity to stent 10. Additional strength and rigidity are especially important at the ends of the stent to prevent 30 deformation of the stent both during delivery and after placement. During delivery the stent ends can catch on the vessel wall possibly deforming the

unexpanded stent and altering its expansion characteristics. After the stent has been placed it is important that the stent ends are rigid so that they set firmly against the vessel wall; otherwise, during a subsequent catheter procedure, the catheter or guidewire can catch on the stent ends pulling the stent away from the vessel wall and possibly damaging and/or blocking the vessel.

The specific variation of the third embodiment of stent 10 depicted in Figures 6A and 6B has a length 16 of 20.70 mm and an uncrimped and unexpanded circumference 88 of 5.26 mm. The stent 10 consists of six expansion columns 24 and three reinforcement expansion columns 86, each 10 consisting respectively of twelve expansion struts 28 or reinforcement expansion struts 90. The reinforcement expansion columns 86 are positioned one at either end, and one along the length of the stent 10.

The expansion strut width 62 is .15 mm, reinforcement expansion strut width 92 is .20 mm, and the connecting strut width 66 is .10 mm. The narrow angle 48 formed by joining strut 30 and expansion strut 28 is 75 degrees, and the narrow angle 94 formed by reinforcement joining strut 96 and reinforcement expansion strut 90 is 60 degrees.

Other arrangements of reinforcement expansion columns 86, such as 20 providing reinforcement expansion columns 86 only on the ends of the stent, only on one end, or at multiple locations throughout the length of the stent can also be used and fall within the scope of the present invention. A taper can also be programmed into the reinforced stent 10 by shortening expansion struts 28 and reinforcement expansion struts 90 in appropriate expansion columns 24 and 86.

A fourth embodiment of the present invention, shown in the Figures 7A, 25 7B and 7C, is similar to the third embodiment but has the added feature of relief notches 98 and 100. A relief notch is a notch where metal has been removed from a strut, usually at a joint where multiple struts are connected. Relief notches increase flexibility of a strut or joint by creating a thinned, narrow region 30 along the strut or joint. Relief notch 98 is formed at the joint formed between first linear section 54 of connecting strut 38 and expansion strut 28. Relief notch

100 is formed at the joint between second linear section 56 of connecting strut 38 and expansion strut 28. The positioning of the relief notches gives added flexibility to the unexpanded stent. Relief notches can be placed at other joints and can be included in any of the previously mentioned embodiments.

5 Figures 8A, 8B, 8C, 8D and 8E illustrates some examples of alternate connecting strut designs which can be used in any of the previously discussed embodiments. Figure 8A shows a rounded loop connecting strut 38 which joins two circumferentially offset expansion strut pairs 32 in adjacent expansion columns. Expansion struts 28 in each expansion strut pair 32 are joined by a joining strut 30. Joining struts 30 are slanted such as to form a narrow angle 48 and a wide angle 50 with the expansion struts 28 they connect. The rounded loop connecting strut 38 connects expansion struts 28 at the point where narrow angle is formed between expansion strut 28 and joining strut 30. The slopes of the rounded connecting strut 38 at its proximal end 102 and distal end 104 substantially match the slopes of the joining struts 30 connecting the pairs of expansion struts 28. The rounded loop connecting strut 38 thus blends smoothly into the joining struts 30. Additionally the rounded loop connecting strut 38 has a first radius of curvature 106 and a second radius of curvature 108.

10

15

20 In the design of Figure 8B a rounded loop connecting strut 38 joins two circumferentially offset expansion strut pairs 32 in adjacent expansion columns. Expansion struts 28 in each expansion strut pair 32 are joined by a joining strut 30. Joining struts 30 are at right angles to the expansion struts 28 they connect. The rounded loop connecting strut 38 connects to expansion struts 28 at the same point as joining struts 30. The rounded connecting strut 38 has a first radius of curvature 106 and a second radius of curvature 108 such that it connects circumferentially offset expansion strut pairs 32.

25

30 In the design of Figure 8C connecting strut 38 joins two circumferentially offset expansion strut pairs 32 in adjacent expansion columns. Expansion struts 28 in each expansion strut pair 32 are joined by a joining strut 30. Joining struts 30 are slanted such as to form a narrow angle 48 and a wide angle 50 with the expansion struts 28 they connect. The connecting strut 38

connects expansion struts 28 at the point where narrow angle 48 is formed between expansion strut 28 and joining strut 30.

The connecting strut 38 is made up of three linear sections 110, 112, and 114 forming two slant angles 116 and 118. The proximal end of section 110 is attached to expansion strut 28 at the point where joining strut 30 forms narrow angle 48 with expansion strut 28. Section 110 extends substantially collinear to joining strut 30 and is attached at its distal end to section 112 forming slant angle 116. Section 112 extends at an angle to section 110 such that section 112 is substantially parallel to expansion struts 28 and is connected at its distal end to the proximal end of section 114 forming slant angle 118. Section 114 extends at an angle such that it is substantially collinear to joining strut 30 of the adjacent expansion strut pair 32. Section 114 attaches at its distal end to expansion strut 28 of the adjacent expansion strut pair 32, at the point where joining strut 30 forms narrow angle 48 with expansion strut 28.

In the design of Figures 8D and 8E a connecting strut 38 joins two circumferentially offset expansion strut pairs 32 in adjacent expansion columns. Expansion struts 28 in each expansion strut pair 32 are joined by a joining strut 30. Joining struts 30 are at right angles to the expansion struts 28 they connect. The connecting strut 38 connects to expansion struts 28 at the same point as joining struts 30.

The connecting struts 38 of Figures 8D and 8E are made up of multiple connecting strut sections connected end to end to form a jagged connecting strut 38 with multiple slant angles, coupling expansion strut pair 32 to adjacent expansion strut pair 32. The connecting strut of Figure 8D is made up of three connecting strut sections 120, 122, and 124 with two slant angles 126 and 128, while the connecting strut of Figure 8E consists of four connecting strut sections 130, 132, 134, and 136 with three slant angles 138, 140 and 142. In addition, the connecting strut section 134 can be modified by replacing connecting strut section 136 by the dotted connecting strut section 144 to give another possible geometry of connecting struts 38.

One skilled in the art will recognize that there are many possible arrangements of connecting struts and joining struts consistent with the present invention; the above examples are not intended to be an exhaustive list.

5 The stent of the present invention is ideally suited for application in coronary vessels although versatility in the stent design allows for applications in non-coronary vessels, the aorta, and nonvascular tubular body organs.

10 Typical coronary vascular stents have expanded diameters that range from 2.5 to 5.0 mm. However, a stent with high radial strength and fatigue tolerance that expands to a 5.0 mm diameter may have unacceptably high stent metal fraction when used in smaller diameter vessels. If the stent metal fraction is high, the chances of acute thrombosis and restenosis potential will increase. Even with the same metal fraction a smaller caliber vessel is more likely than a larger one to have a high rate of thrombosis. It is, therefore, preferred to have at least two different categories of stents for coronary application, for example, 15 small vessels stents for use in vessels with diameters from 2.5 mm to 3.0 mm, and large vessel stents for use in vessels with diameters from 3.0 mm to 5.0 mm. Thus, both small vessels and large vessels when treated with the appropriate sized stent will contain stents of similar idealized metal fraction.

20 The stent of the present invention can be made using a CAM-driven laser cutting system to cut the stent pattern from a stainless steel tube. The rough-cut stent is preferably electro-polished to remove surface imperfections and sharp edges. Other methods of fabricating the stent can also be used such as EDM, photo-electric etching technology, or other methods. Any suitable material can be used for the stent including other metals and polymers so long as they provide 25 the essential structural strength, flexibility, biocompatibility and expandability.

30 The stent is typically at least partially plated with a radiopaque metal, such as gold, platinum, tantalum or other suitable metal. It is preferred to plate only both ends of the stent by localized plating; however, the entire stent or other regions can also be plated. When plating both ends, one to three or more expansion columns on each end of the stent are plated to mark the ends of the stent so they can be identified under fluoroscopy during the stenting procedure.

By plating the stent only at the ends, interference of the radiopaque plating material with performance characteristics or surface modulation of the stent frame is minimized. Additionally the amount of plating material required is reduced, lowering the material cost of the stent.

5 After plating, the stent is cleaned, typically with detergent, saline and ultrasonic means that are well-known in the art. The stents are then inspected for quality control, assembled with the delivery balloon catheter, and properly packaged, labeled, and sterilized.

10 The stent can be marketed as stand alone or as a pre-mounted delivery balloon catheter assembly as shown in Figure 9. Referring to Figure 9, the stent 10 is crimped over a folded balloon 146 at the distal end 148 of a delivery balloon catheter assembly 150. The assembly 150 includes a proximal end adapter 152, a catheter shaft 154, a balloon channel 156, a guidewire channel 158, a balloon 146, and a guidewire 160. Balloon 146 can be tapered, curved, 15 or both tapered and curved from a proximal end to a distal end in the expanded state. Additionally stent 10 can be non-tapered or tapered in the expanded state

20 Typically the guidewire 160 is inserted into the vein or artery and advanced to the target site. The catheter shaft 154 is then forwarded over the guidewire 160 to position the stent 10 and balloon 146 into position at the target site. Once in position the balloon 146 is inflated through the balloon channel 156 to expand the stent 10 from a crimped to an expanded state. In the expanded state, the stent 10 provides the desired scaffolding support to the vessel. Once the stent 10 has been expanded, the balloon 146 is deflated and the catheter shaft 154, balloon 146, and guidewire 160 are withdrawn from the patient

25 The stent of the present invention can be made as short as less than 10 mm in length or as long as 100 mm or more. If long stents are to be used, however, matching length delivery catheter balloons will typically be needed to expand the stents into their deployed positions. Long stents, depending on the target vessel, may require curved long balloons for deployment. Curved balloons which match the natural curve of a blood vessel reduce stress on the blood vessel during stent deployment. This is especially important in many

coronary applications which involve stenting in curved coronary vessels. The use of such curved balloons is within the scope of the present invention.

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

What is claimed is:

10

CLAIMS

1. A stent in a non-expanded state, comprising:
 - 5 a first expansion strut pair including a first expansion strut positioned adjacent to a second expansion strut and a joining strut of the first expansion strut pair that couples the first and second expansion struts at a distal end of the first expansion strut pair, a plurality of the first expansion strut pair forming a first expansion column;
 - 10 a second expansion strut pair including a first expansion strut positioned adjacent to a second expansion strut and a joining strut of the second expansion strut pair that couples the first and second expansion struts of the second expansion strut pair at a proximal end of the second expansion strut pair, a plurality of the second expansion strut pair forming a second expansion column;
 - 15 a first connecting strut including a first connecting strut proximal head section and first connecting strut distal tail section, the head section being coupled to the distal end of the first expansion strut pair in the first expansion column and the tail section being coupled to the proximal end of the second expansion strut pair of the second expansion column, a plurality of the first connecting strut forming a first connecting strut column that couples the first expansion column to the second expansion column, the tail section extending in a first lateral direction relative to a longitudinal axis of the head section to form a first slant angle;
 - 20 a third expansion strut pair including a first expansion strut positioned adjacent to a second expansion strut and a third joining strut of the third expansion strut pair that couples the first and second expansion struts at a proximal end of the third expansion strut pair, a plurality of the third expansion strut pair forming a third expansion column, the first expansion strut of the first expansion strut pair in the first expansion column having a longitudinal axis that is parallel to and offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column, and the second expansion strut of the third expansion strut pair in the third expansion column having a

longitudinal axis that is parallel to and offset from a longitudinal axis of the first expansion strut of the second expansion strut pair of the second expansion column;

5 a second connecting strut including a proximal head section and a distal tail section, the head section being coupled to the distal end of the second expansion strut pair in the second expansion column and the tail section being coupled to the proximal end of the third expansion strut pair of the third expansion column, a plurality of the second connecting strut forming a second connecting strut column that couples the second expansion column to the third expansion column, wherein the tail section extends in a second lateral direction relative to a longitudinal axis of the head section to form a second slant angle that extends in an opposite direction from the first lateral direction; and
10 wherein a ratio of a number of expansion struts in an expansion strut column to a number of connecting struts in a connecting strut column is 2 to 1 and the first slant angle reduces a fore shortening of the stent between the first and second expansion columns when the stent is in an expanded state.
15

2. The stent of claim 1, wherein the stent includes m first and second expansion columns, n expansion struts per column and $n(m-1)/2$ connecting struts.
20

3. The stent of claim 1, wherein the first and second expansion columns are each unbroken, continuous structures.

25 4. The stent of claim 1, wherein each of the first slant angles is directed in a first circumferential direction.

5. The stent of claim 1, wherein the first connecting strut includes a third slant angle.

6. The stent of claim 1, wherein a width of a portion of the first connecting struts is equal to or less than a width of a portion of the first expansion struts.

5 7. The stent of claim 1, wherein a width of a portion of the first connecting struts is larger than a width of a portion of the first expansion struts.

10 8. The stent of claim 1, wherein a width of a portion of the second expansion struts is substantially the same as a width of a portion of the first expansion struts.

15 9. The stent of claim 1, further comprising a reenforcement expansion column made of a plurality of reenforcement expansion struts, wherein each reenforcement expansion strut has a width that is greater than a width of an expansion strut in the first or second expansion columns.

20 10. The stent of claim 1, wherein the stent has a proximal end with a first reenforcement expansion column and a distal end with a second reenforcement expansion column.

11. The stent of claim 1, wherein at least a portion of the first connecting struts have a first radius of curvature.

25 12. The stent of claim 11, wherein the portion of the first connecting struts with the first radius of curvature have a second radius of curvature.

30 13. The stent of claim 1, wherein at least a portion of the first connecting struts have first linear sections coupled to joining struts of first expansion strut pairs and second linear sections coupled to joining struts of second expansion strut pairs.

5

14. The stent of claim 1, wherein at least a portion of the first connecting struts have first linear sections coupled to joining struts of first expansion strut pairs, second linear sections coupled to joining struts of second expansion strut pairs and third linear sections coupling the first and second linear sections.

10

15. The stent of claim 1, wherein at least a portion of the first connecting struts have first linear sections coupled to joining struts of first expansion strut pairs, second linear sections coupled to joining struts of second expansion strut pairs, third and fourth linear sections coupling the first and second linear sections.

15

16. The stent of claim 1, wherein the stent further includes a radiopaque marker.

20

17. The stent of claim 1, wherein the stent includes an electroplated material.

25

18. The stent of claim 1, wherein in an expanded state the stent has a tapered diameter.

30

19. A stent assembly, comprising:
a balloon; and
an expandable stent positioned at an exterior of the balloon, the stent including,

a first expansion strut, a plurality of the first expansion strut forming a first expansion column;

a second expansion strut, a plurality of the second expansion strut forming a second expansion column; and

a first connecting strut, a plurality of the first connecting strut forming a first connecting strut column, each of a first connecting strut

5

connecting a first expansion strut of the first expansion column to a second expansion strut of the second expansion column, the first connecting strut including a proximal section coupled to a distal section and at least a portion of the first connecting strut including a first linear section and a first slant angle.

10

20. The assembly of claim 19, wherein the balloon has a tapered geometry.

15

21. The assembly of claim 19, wherein a proximal end and a distal end of the connecting strut are circumferentially offset from each another when the stent is in a non-expanded state.

15

22. The assembly of claim 19, wherein a proximal end and a distal end of the connecting strut are circumferentially offset from each another when the stent is in an expanded state.

20

23. The assembly of claim 19, wherein a ratio of a number of expansion struts in an expansion strut column to a number of connecting struts in an connecting strut column is 2 to 1.

25

24. The assembly of claim 19, wherein the connecting strut has a geometry which provides for a reduction of a fore shortening of the stent between the first and second expansion columns when the stent is in an expanded state.

30

25. The assembly of claim 19, wherein the stent includes m first and second expansion columns, n expansion struts per column and $n(m-1)/2$ connecting struts.

26. The stent of claim 19, wherein the first and second expansion columns are each unbroken, continuous structures.

5 27. The stent of claim 19, wherein each first connecting strut first slant angle is directed in a first circumferential direction.

10 28. The stent of claim 19, wherein the first connecting strut includes a second slant angle.

15 29. The stent of claim 19, wherein the first expansion strut of the first expansion column is longitudinally offset from a corresponding second expansion strut of the second expansion column.

30. The stent of claim 1, wherein the stent has a tapered diameter in an expanded state.

15 31. The stent of claim 1, wherein the stent has a tapered geometry extending from a proximal end to a distal end in an expanded state.

20 32. The stent assembly of claim 19, wherein the balloon is tapered in an expanded state.

25 33. The stent assembly of claim 32, wherein the balloon in an expanded state is curved along a longitudinal axis from a proximal end to a distal end.

34. The stent assembly of claim 32, wherein the balloon is tapered in an expanded state and the stent has a non-tapered geometry in an expanded state.

35. The stent assembly of claim 32, wherein the balloon and the stent are both tapered in an expanded state.

5 36. The stent assembly of claim 33, wherein the stent is non-tapered in an expanded state.

37. The stent assembly of claim 33, wherein the stent is tapered in an expanded state.

10 38. The stent of claim 1, wherein the stent includes an electroplated material at a stent proximal end and at a stent distal end.

15 39. A stent in a non-expanded state, comprising:
a first column expansion strut pair, a plurality of the first column expansion strut pair forming a first expansion column;
a second column expansion strut pair, a plurality of the second column expansion strut pair forming a second expansion column; and
20 a first connecting strut a plurality of first connecting struts forming a first connecting strut column, the plurality of first connecting struts coupling the first expansion column to the second expansion column; and
wherein the first expansion column, the second expansion column, and the first connecting strut column provide a low profile when crimped over a balloon.

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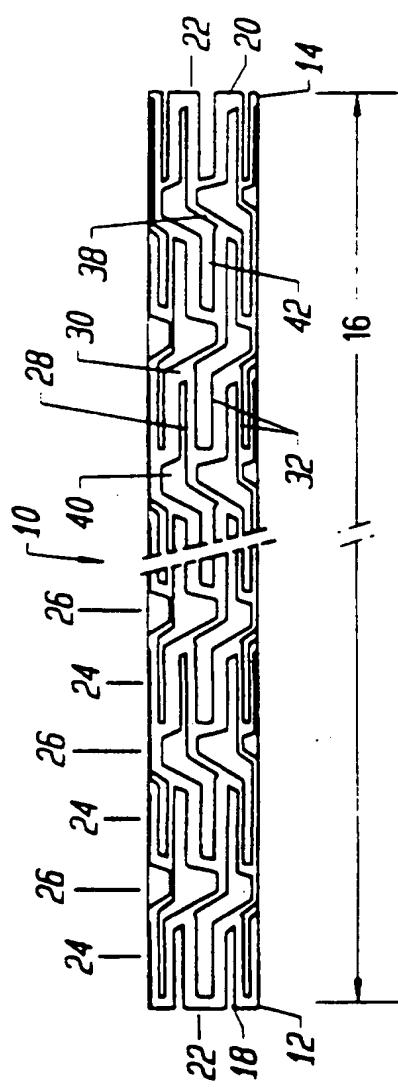


FIG. 1A

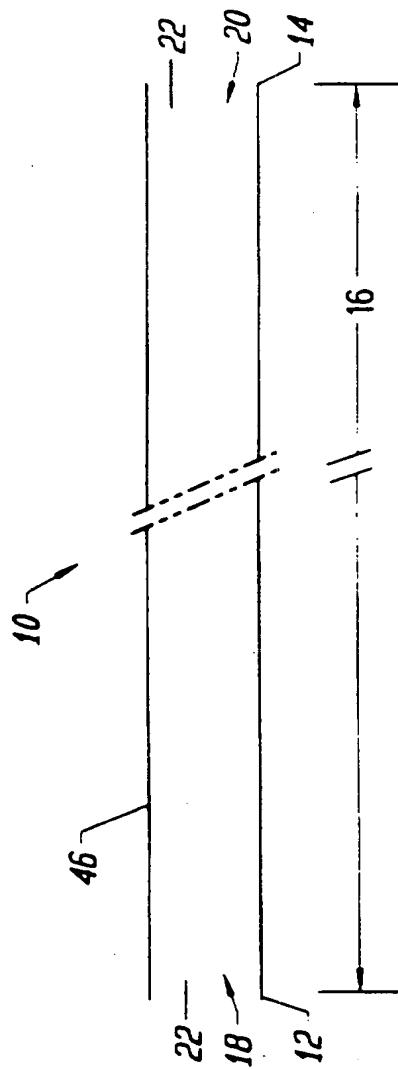


FIG. 1B

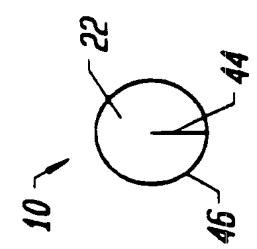
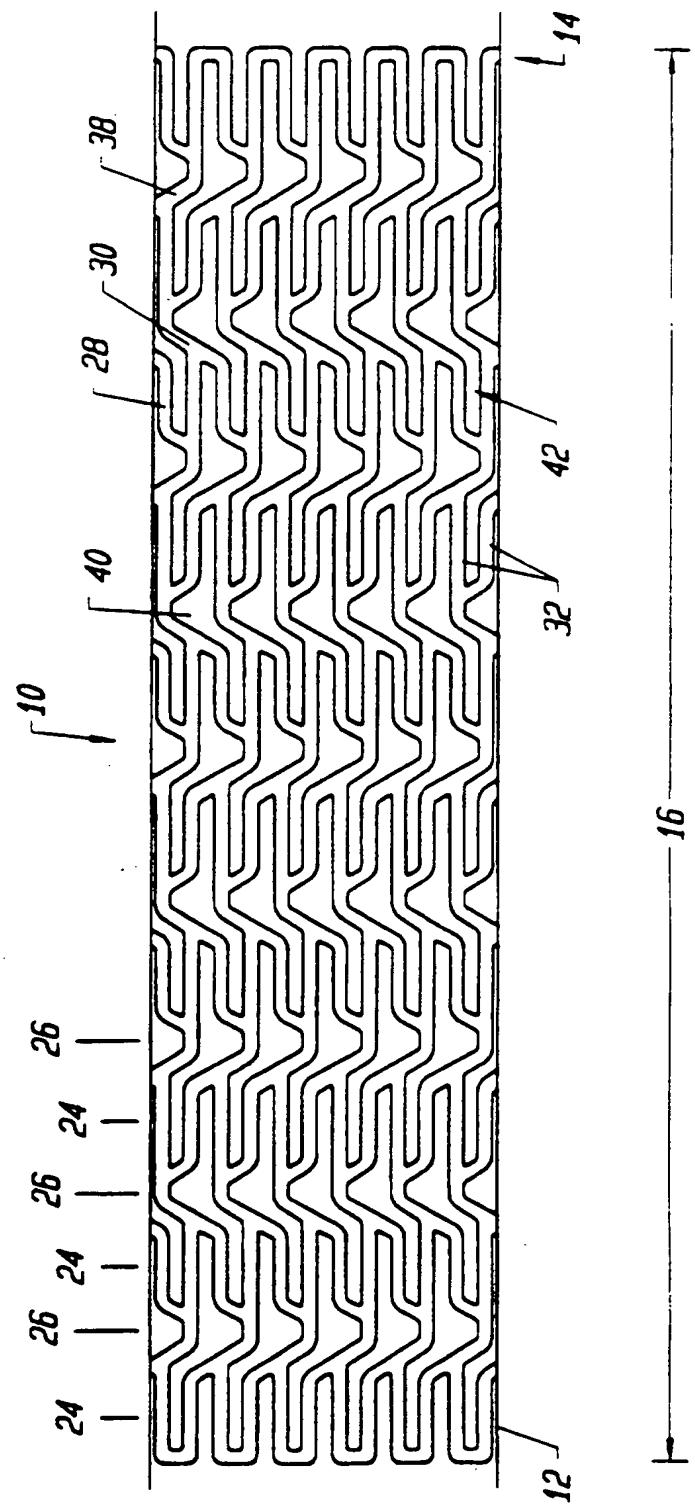


FIG. 1C

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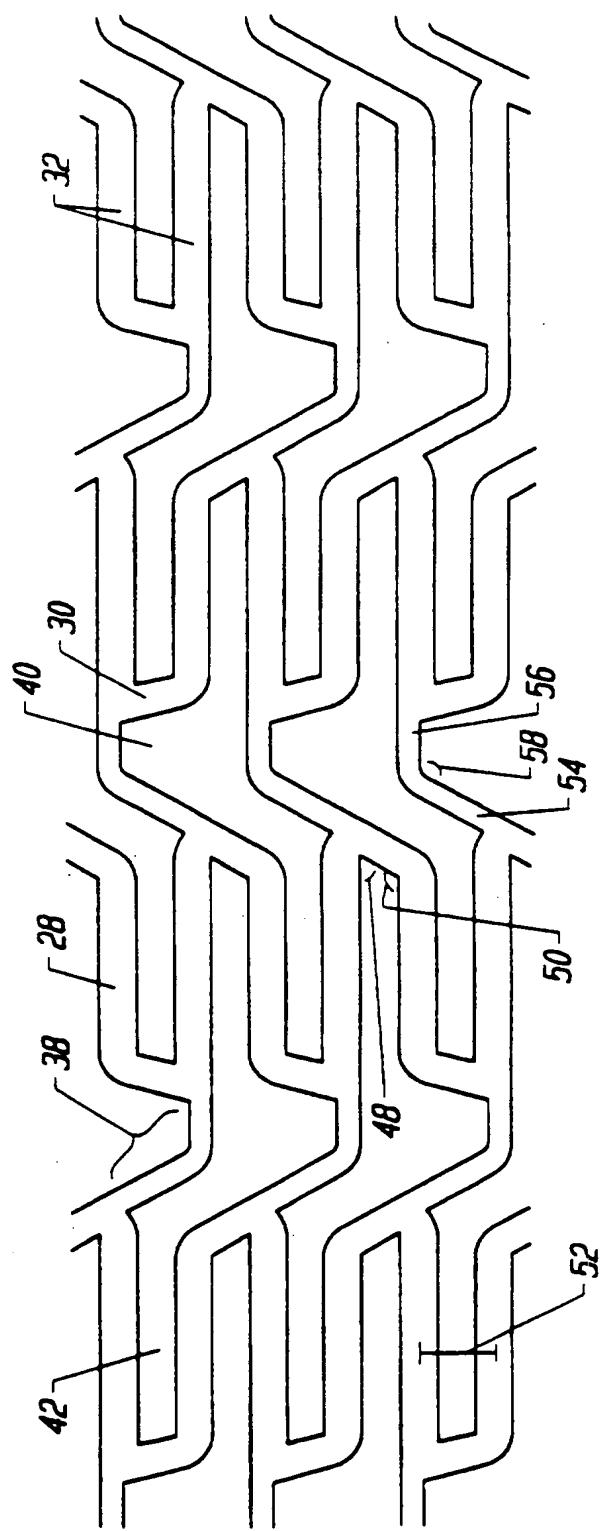


FIG. 2B

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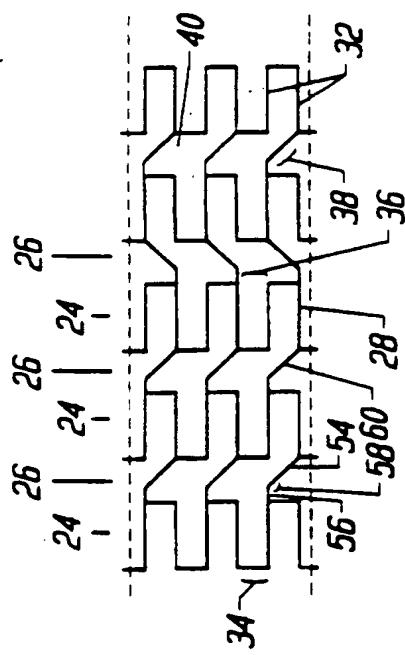
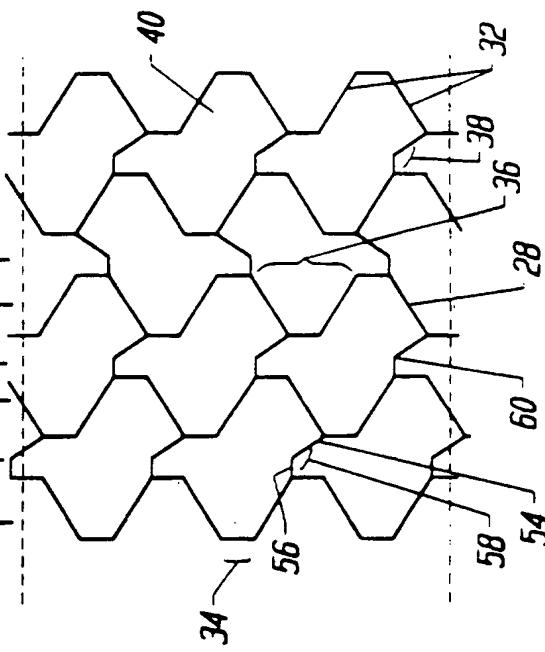
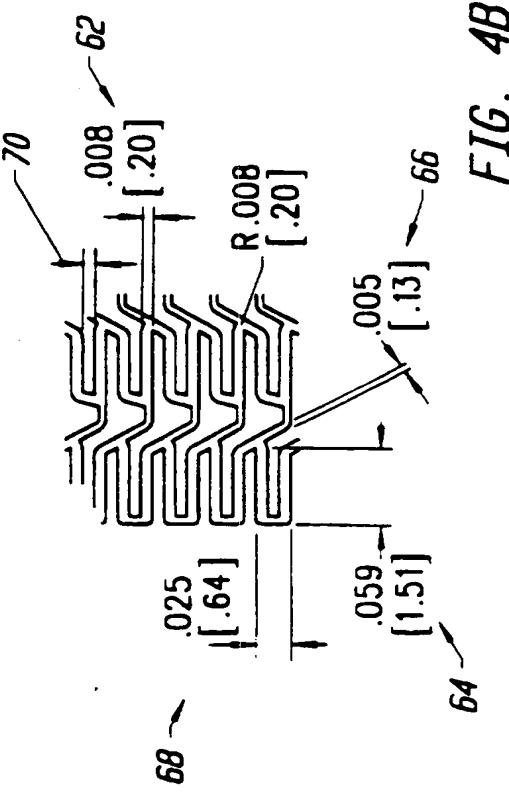
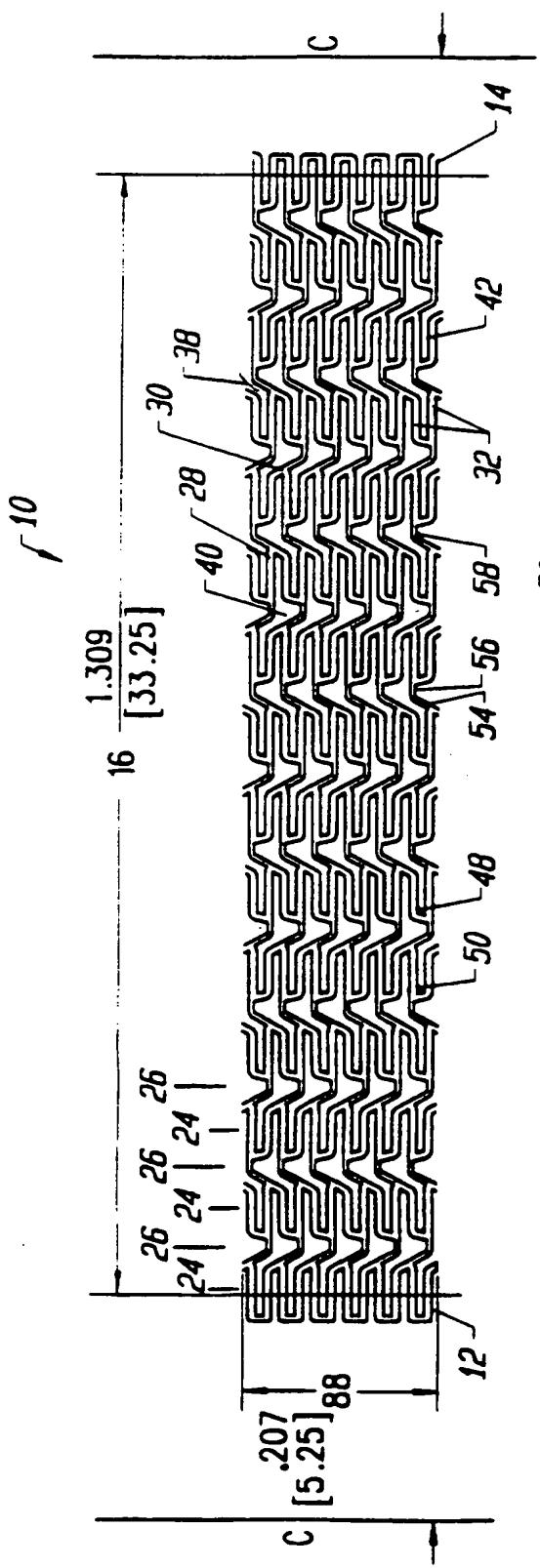


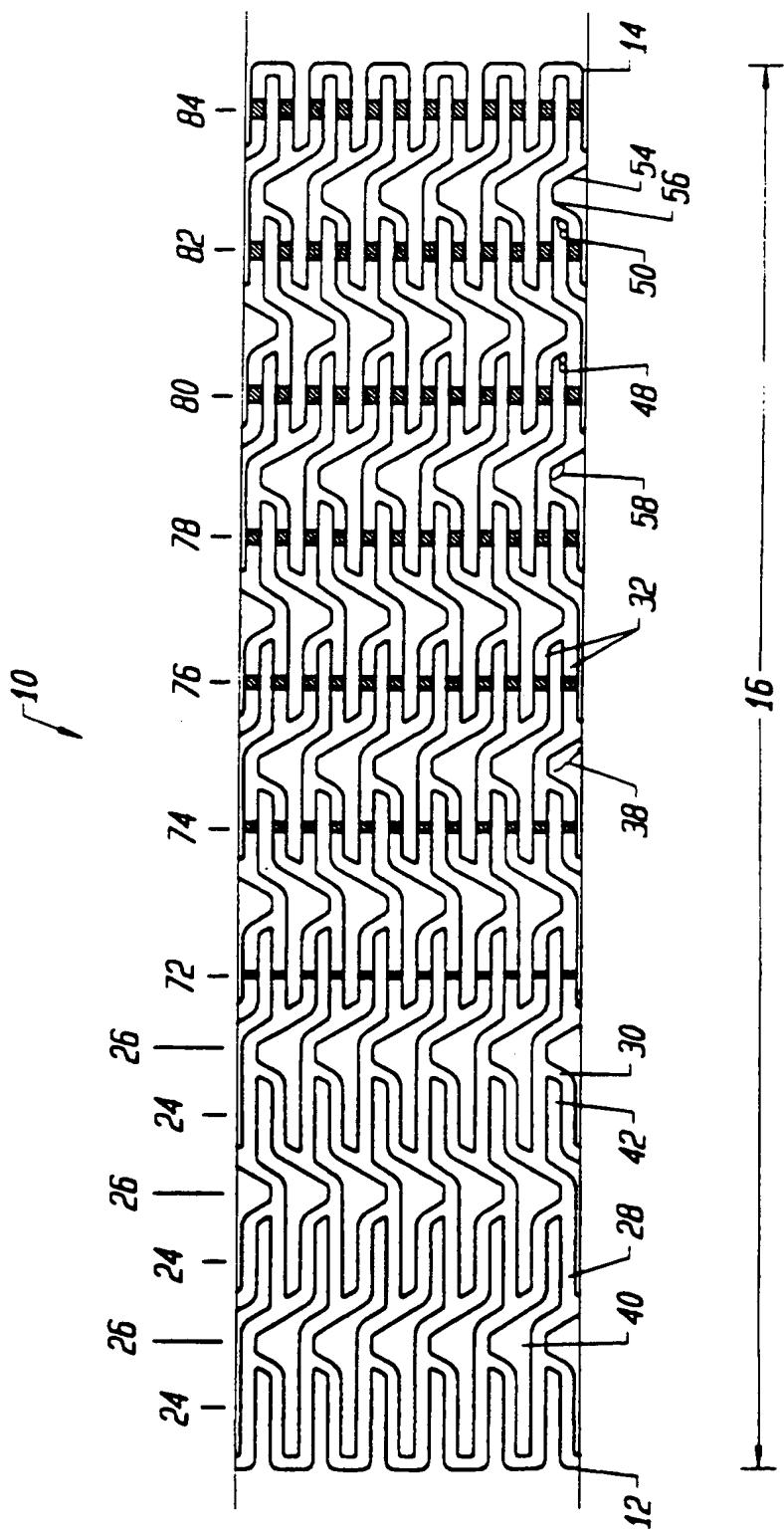
FIG. 3A

FIG. 3B

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SUBSTITUTE SHEET (RULE 26)

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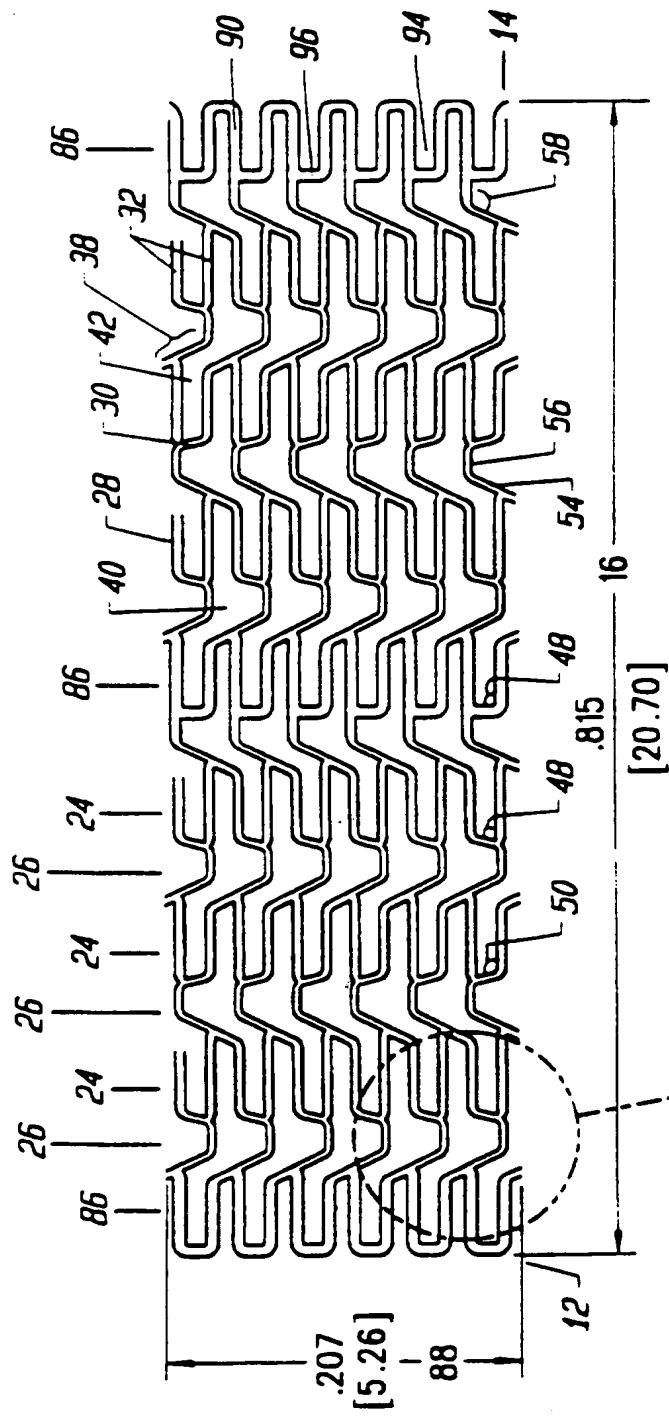
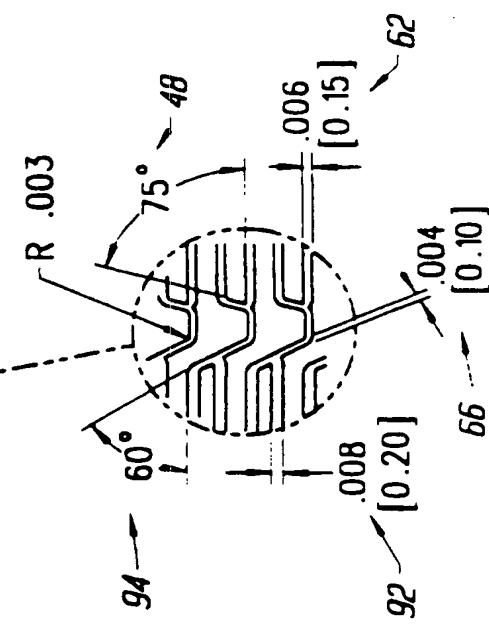


FIG. 6A



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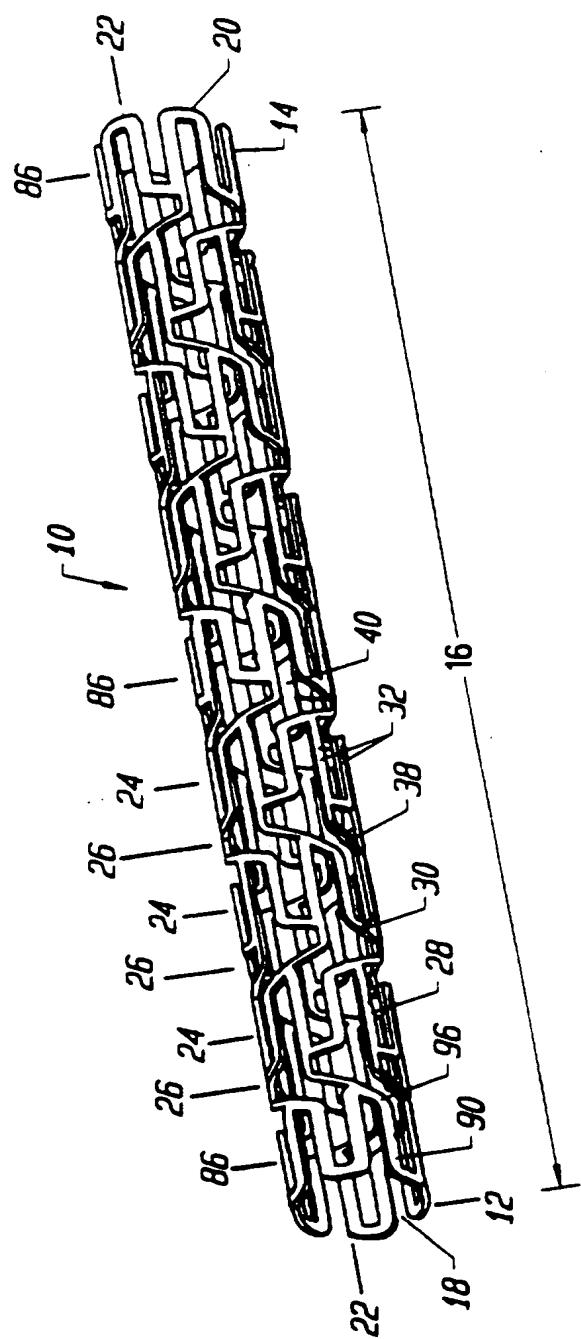


FIG. 6B

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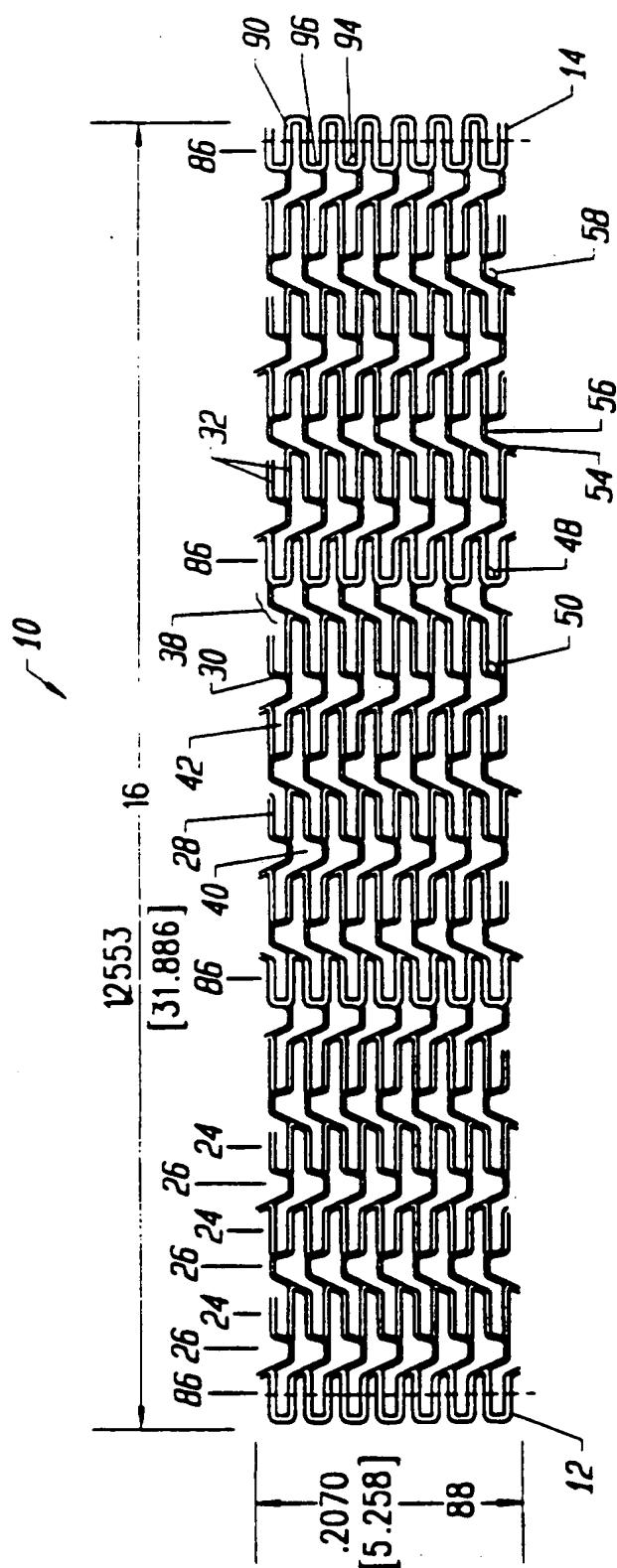


FIG. 7A

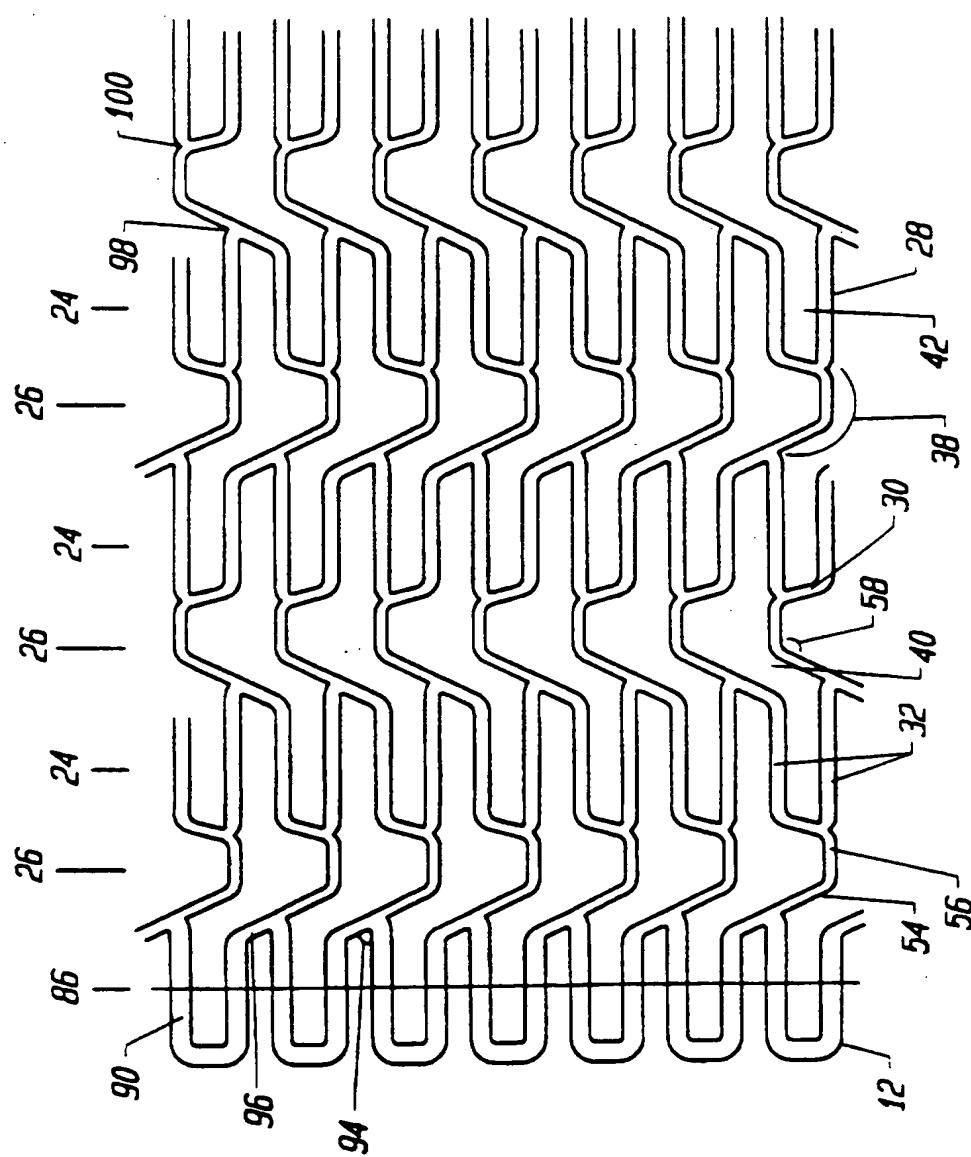


FIG. 7B

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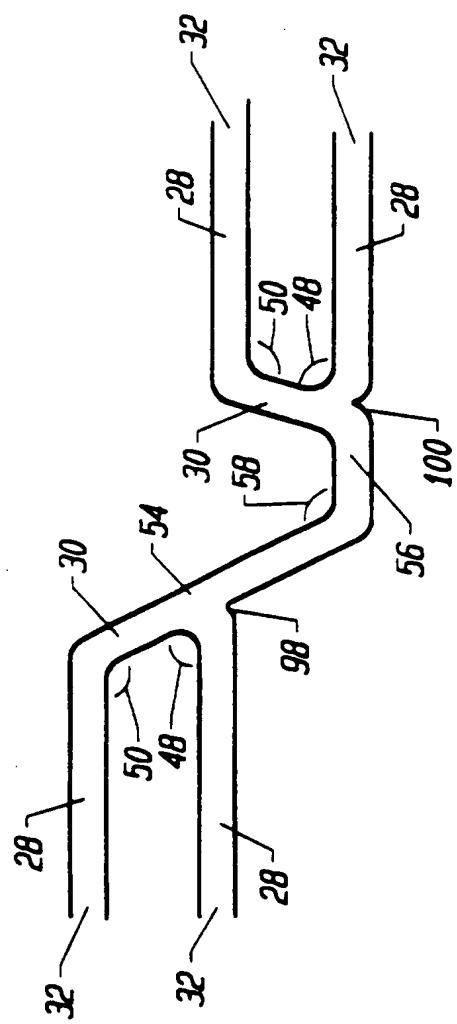
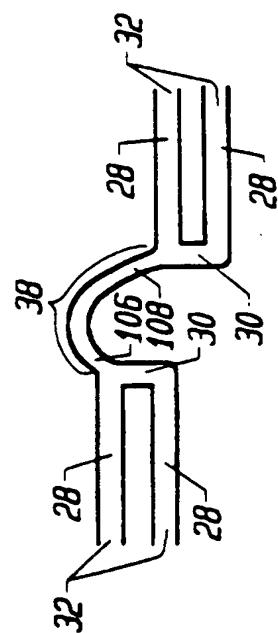
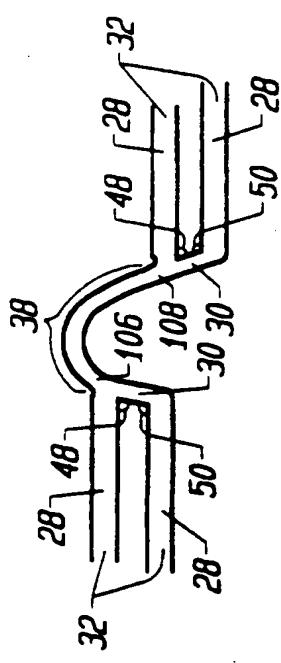


FIG. 7C

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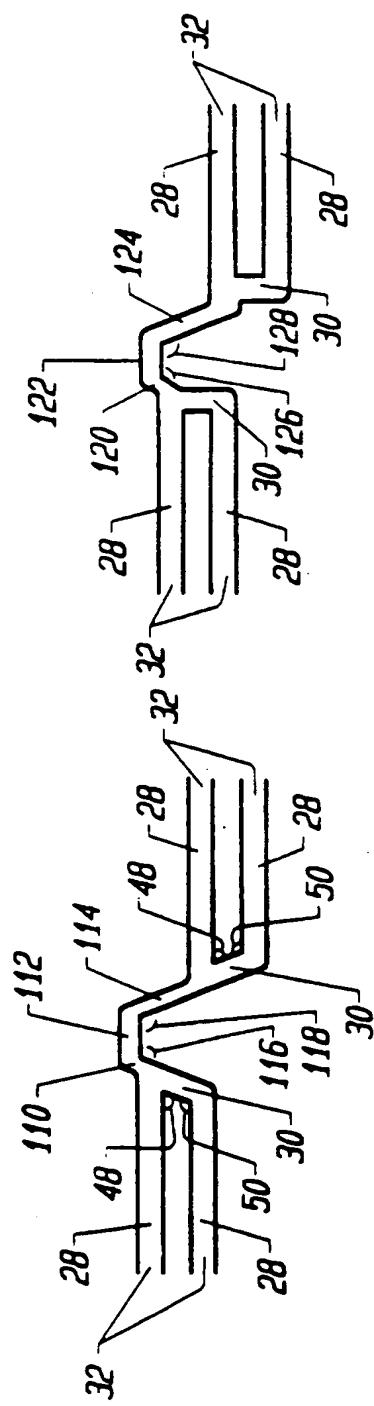


FIG. 8C

FIG. 8D

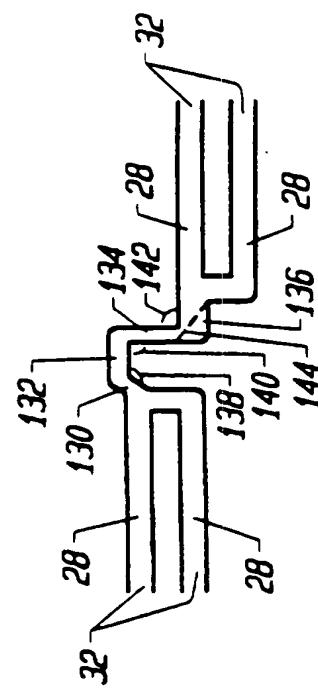


FIG. 8E

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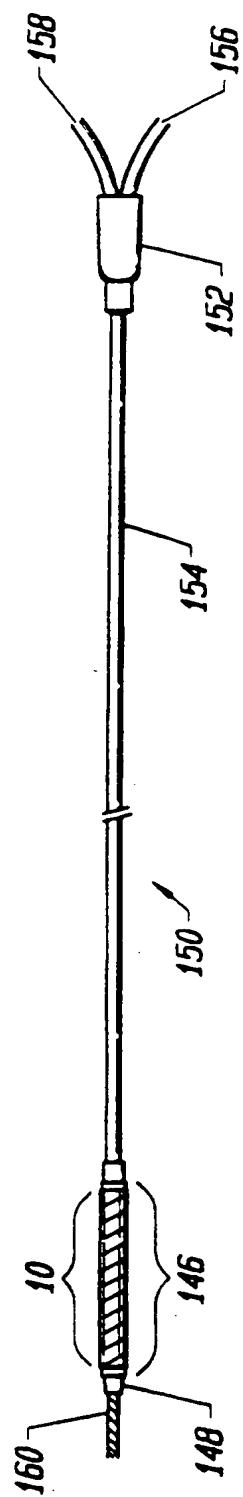


FIG. 9

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/06610

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 449 373 A (PINCHASIK ET AL.) 12 September 1995	19.23, 25-28,39
A	see the whole document ---	1
A	EP 0 587 197 A (ANGIOMED) 16 March 1994 see column 2, line 52 - line 56; figure 2 -----	30,31

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- *'A' document defining the general state of the art which is not considered to be of particular relevance
- *'E' earlier document but published on or after the international filing date
- *'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *'O' document referring to an oral disclosure, use, exhibition or other means
- *'P' document published prior to the international filing date but later than the priority date claimed

*'T' later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

*'X' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

*'Y' document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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